

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)
PAR STERILE PRODUCTS, LLC, and)
ENDO PAR INNOVATION)
COMPANY, LLC,)
Plaintiffs,) C.A. No. 18-823-CFC
)
v.)
)
EAGLE PHARMACEUTICALS INC.,)
)
Defendant.)

PUBLIC VERSION

PAR PHARMACEUTICAL, INC.,)
PAR STERILE PRODUCTS, LLC, and)
ENDO PAR INNOVATION)
COMPANY, LLC,)
Plaintiffs,) C.A. No. 18-2032-CFC
)
v.)
)

PUBLIC VERSION

AMNEAL PHARMACEUTICALS OF)
NEW YORK, LLC, et al.,)
Defendants.)

**LETTER TO THE HONORABLE COLM F. CONNOLLY
FROM BINDU A. PALAPURA**

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VIA ELECTRONIC FILING

The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

PUBLIC VERSION

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823;
Par Pharm., Inc. v. Amneal Pharm., C.A. No. 18-2032 (Cons.)

Dear Chief Judge Connolly:

On behalf of both Defendants, we respectfully submit this brief reply to Par's August 3 letter (18-823 D.I. 292). While Defendants are hesitant to burden the Court with another filing, Par's letter contains significant misstatements that Defendants believe warrant correction.

First, Par's letter now seeks to greatly expand the scope of its noticed objections. In correspondence on this issue, and in its responsive Proposed Findings of Fact, Par objected only to Defendants' reliance on ***6- and 9-month impurity data*** for Original Vasostrict Lot 788435. (See 18-823 D.I. 285 ¶¶92–98, 100–106; 18-823 D.I. 291, Ex. A.)¹ Yet, Par's letter purports to expand that objection to ***any*** reliance by Defendants on that lot's impurities for obviousness purposes, including ***the 12-month impurity data*** on Lot 788435, on which Par's expert, Dr. Kirsch, was specifically cross-examined *without objection*. (Kirsch Tr. 857:18–62:8.) The time for such an expansive objection has long since passed. Eagle provided clear notice of its intention to rely on the impurities of Lot 788435—for which Par had improperly withheld sales records showing it was prior art until the eve of the prior-scheduled trial (*see infra*)—for obviousness purposes in the revised Pretrial Order. (18-823 D.I. 268, Ex. 3, ¶¶ 200, 207–08, 234.) Contrary to Par's assertion that Eagle “slipped in” the reference to Lot 788435's impurities, Eagle provided a redline of its

¹ Par also accuses Defendants of looking to save these findings for “Washington,” but Eagle's invalidity theory based on the batch data was discussed extensively at trial, consistent with the Court's rule. Moreover, if Par were right, Defendants would not have put it in their proposed findings for this Court to decide.

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amendments for the specific purpose of alerting Par to them. (Ex. A.) Par did not object. Nor did Par object when Defendants cross-examined Dr. Kirsch on the impurities data for Lot 788435. (Kirsch Tr. 857:18–62:8.) Had Par timely objected, the issues it newly raises could have been addressed at the Pretrial Conference or during trial, rather than after trial when the record is complete, and post-trial briefing filed.

Second, Par’s allegation that Defendants have “transformed” their invalidity case around Lot 788435 is incorrect. Defendants have long-maintained the asserted patents are obvious over commercially sold Original Vasostrict. But because Par has pulled that product from the market and—as it repeatedly emphasized at trial and in its post-trial briefing (*see, e.g.*, Tr. 424:10–14, 431:7–22; 18-823 D.I. 285 at 9; 18-823 D.I. 286 ¶272)—the stability and sales data for its commercial lots are not public, Defendants had to rely on Par’s compliance with its discovery obligations to identify which lots were in fact sold, and the properties of those commercial lots. What Par does not mention in its letter is that, despite repeated requests for Original Vasostrict sales data, Par withheld the sales records for Lot 788435 and other similar lots—which were necessary to confirm those lots as prior art—from Eagle until *just days* before the rescheduled trial date in February. (Ex. B; DTX-1362.) That is why Lot 788435 was not specifically discussed in Eagle’s contentions and expert reports, which were due months before Par finally produced the sales data.

Finally, Par’s assertion that Defendants did “not meet and confer with Par” and “simply filed the[ir] letter shortly after the parties made their [post-trial] submissions” is not true. Defendants **did** meet and confer with Par on its objection, followed up to inquire if Par was standing on the objection and, if so, how it would raise the issue with the Court, and even proposed a further meet-and-confer to discuss. (18-823, D.I. 291, Ex. A at 1–5.) Par ignored the request for a second meet-and-confer, instead informing Defendants it had “made no firm decision as to how to proceed.” (*Id.* at 1.) But in less than 24 hours after providing this response, Par proceeded to raise its objection in its *responsive* Proposed Findings of Fact—to which Defendants had no opportunity to respond—without warning.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/7317296/45185

Enclosures

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)